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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/099,836	03/15/2002	Jean-Louis Dasseux	9196-0022-999	5585
28880	7590	06/01/2006	EXAMINER	
WARNER-LAMBERT COMPANY 2800 PLYMOUTH RD ANN ARBOR, MI 48105			LIU, SUE XU	
			ART UNIT	PAPER NUMBER
			1639	

DATE MAILED: 06/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/099,836

Applicant(s)

DASSEUX ET AL.

Examiner

Sue Liu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 March 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-9,12-17,29,34,35,37,42 and 57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-9,12-17,29,34,35,37,42 and 57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Status

1. Claims 1, 3-9, 12-17, 29, 34, 35, 37, 42, and 57 are currently pending;

Claims 1, 3-9, 12-17, 29, 34, 35, 37, 42, and 57 are being examined in this application.

Withdrawal of Finality of the Last Office Action

2. New rejections are deemed necessary upon further consideration, and therefore the finality of the last office action is withdrawn.

Terminal Disclaimer Acknowledgement

3. Applicants have submitted terminal disclaimer for the following Patents and Applications to overcome the double patenting rejections as set forth in the previous office actions:

6,844,327 and 10/099,574.

Claim Rejections Withdrawn (ODP Rejections)

4. Therefore, the following obviousness-type double patenting rejections are withdrawn:
A.) Claims 1, 3-9, 12-16, 17, 29, 34, 35, 37, 42 and 57 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 (especially claims 1, 7-15 and 23) of US Pat. No. 6,844,327 in view of Garber et al., Arteriosclerosis & Thrombosis, Vol. 12(8) (1992) pages 886-94. The obviousness-type double patenting rejection is withdrawn due to the filing of a terminal disclaimer (filed on 3/21/06).

B.) Claims 1, 3-9, 12-16, 17, 29, 34, 35, 37 and 42 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-55 (particularly claims 1-18 and 28-42) of copending application 10/099,574 in view of Garber et al., Arteriosclerosis & Thrombosis, Vol. 12(8) (1992) pages 886-94. The obviousness-type double patenting rejection is withdrawn due to the filing of a terminal disclaimer (filed on 3/21/06).

New Rejections

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 9, 35 and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 recites the limitation "the same sub-category". There is insufficient antecedent basis for this limitation in the claim.

Claim 9 recites the limitations "the substituting D-enantiomeric residue", and "the substituted D-enantiomeric residue". There are insufficient antecedent bases for these limitations in the claim. It is not clear to which D-enantiomeric residue the term "the substituting D-

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enantiomeric residue” (emphasis added) and the term “the substituted D-enantiomeric residue” (emphasis added) are referring.

Claims 35 and 45 recite the limitation "the form". There is insufficient antecedent basis for this limitation in the claim.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

I. Claims 1, 3-9, 12-16, 34, 35, 37, and 57 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-58 of U.S. Patent No. 6,004,925 in view of Garber et al (Arteriosclerosis & Thrombosis. Vol. 12(8) (1992) pages 886-94; cited in previous office actions; PTO892; 10/28/04).

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The Patent ('925) claims disclose compounds and pharmaceutical compositions thereof which are within the scope of the presently claimed 22-29 residue ApoA-I agonist peptide compounds Z1-X1-X23-Z2 (see e.g. Claim 1 of '925). The claims of '925 patent also recites conservative amino acids (see for example, Claim 9 of '925), which reads on the conservative substitution claims of the instant application.

The patented compounds differ from the presently claimed invention by failing to teach the substitution of D-amino acids for L-amino acids.

However, the Garber et al reference provides motivation to one of ordinary skill in the art to substitute D-amino acids for L-amino acids in order to produce Apo-A-I agonist analogs which are "less susceptible to in vivo proteolytic degradation" while retaining comparable biological activity (e.g. residence time; clearance; lipid affinity) to its corresponding L-amino acid containing peptide. See entire Garber article, but particularly, abstract; page 887, left column; Tables 2-4; Figures 1-4; and "Discussion" on pages 891 (right column) to page 893, particularly page 892, right column 2nd full paragraph.

Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to modify the patented compounds (and compositions thereof) to incorporate one or more D-Amino acids in order to obtain Apo-A-I agonist analogues which are less susceptible to in vivo proteolytic degradation while retaining comparable biological activity to the corresponding L-amino acid containing peptides.

II. Claims 1, 3-9, 12-17, 29, 34, 35, 37, 42, and 57 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-48 of U.S. Patent No.

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6,753,313 in view of Garber et al (Arteriosclerosis & Thrombosis. Vol. 12(8) (1992) pages 886-94; cited in previous office actions; PTO892; 10/28/04).

The Patent ('313) claims disclose compounds and pharmaceutical compositions thereof which are within the scope of the presently claimed 22-29 residue ApoA-I agonist peptide compounds X1-X23 (see e.g. Claim 1 of '313). Although the '313 reference does not specifically teach a peptide of formula Z1-X1-X23-Z2 by itself, the peptide (formula I) recited in Claim 1 of '313 reads on the Z1-X1-X23-Z2 formula because Z1 and Z2 can be either the amino or carboxyl end for a peptide as defined in Claim 1. The claims of '313 patent also recites conservative amino acids (see for example, Claim 8 of '313), which reads on the conservative substitution claims of the instant application.

The patented compounds differ from the presently claimed invention by failing to teach the substitution of D-amino acids for L-amino acids.

However, the Garber et al reference provides motivation to one of ordinary skill in the art to substitute D-amino acids for L-amino acids in order to produce Apo-A-I agonist analogs which are "less susceptible to in vivo proteolytic degradation" while retaining comparable biological activity (e.g. residence time; clearance; lipid affinity) to its corresponding L-amino acid containing peptide. See entire Garber article, but particularly, abstract; page 887, left column; Tables 2-4; Figures 1-4; and "Discussion" on pages 891 (right column) to page 893, particularly page 892, right column 2nd full paragraph.

Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to modify the patented compounds (and compositions thereof) to incorporate one or more D-Amino acids in order to obtain Apo-A-1 agonist analogues which

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are less susceptible to in vivo proteolytic degradation while retaining comparable biological activity to the corresponding L-amino acid containing peptides.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sue Liu whose telephone number is 571-272-5539. The examiner can normally be reached on M-F 9am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**PETER PARAS, JR.
PRIMARY EXAMINER**

Pete Paras
SPC1639

SL
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5/18/2006